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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,464	11/29/2000	Kun Ping Lu	BIZ-045CP	1620

959 7590 03/26/2002

LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,464

Applicant(s)

LU ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 27-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-26) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the restriction is improper and does not pose a burden to examine. This is not found persuasive because Group I (claims 1-26) and Group II (claims 27-37) are methods that require different levels of skill in the art. A telephonic interview was made on March 22, 2002, wherein group II has now been changed to claims 27-36, due to an error in the numbering of the groups in the restriction requirement (paper no 7). Group I is drawn to methods of detection, wherein the practitioner is required to determine either the presence/absence or the elevation/depression of Pin1. Group II is drawn to methods of determining, and hence requires some form of diagnosis, a skill associated with deeper cognitive interpretation of data and results, for example staging of cancer (claim 28). Although the groups are classified in the same class and subclass, they are drawn to two patentable distinct concepts.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-26 are being examined on the merits.

Specification

The disclosure is objected to because of the following informalities: priority information needs to be updated in the specification (**Related Applications** section).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In regards to claim 1 and dependent claims thereof, in the recitation of the phrase "*an elevation in the levels*", it is indefinite because it is unclear as to what the levels are compared to. Clarification is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant application is drawn to methods of detecting abnormal cell growth by measuring, assessing or comparing the levels of Pin1 in a test sample and comparing those levels to levels of Pin1 in a control sample. The instant application fails to provide an adequate disclosure to guide one of skill in the art to practice the invention as claimed. Therefore, the instant specification invites the skilled artisan to experiment.

The factors that which must be considered in determining undue experimentation are set forth in *In re Wands* USPQ2d 14000. The factors include 1) quantity of

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experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predicatability of the art, 7) and the breadth of the claims.

With regards to factors one and two cited above the experimentation required to determine the levels of Pin1 that exceed the threshold limit to adequately detect whether a cell is undergoing abnormal cell growth, either through protein levels or through nucleic acid levels has not been provided guidance in the written description for accomplishing and determining such. The instant application does contemplate the use of Pin1 nucleic acid molecules, Pin1 protein and antibodies to Pin1 for detection but does not provides guidance in terms of how to assess the levels and what levels are needed to the differentiate between abnormal versus normal levels of cell growth.

With regards to factors four, five and six, it is noted that there is a great deal of uncertainty, unpredictability, and variability associated with determining levels of abnormal cell growth between samples. The instant application fails to provide specific methodological steps or procedures for which the instant method can or is intended to be used for detecting abnormal cell growth. It is known to those skilled in the art that detection of abnormal cell growth (either benign or malignant) is often difficult and unpredictable in terms of accuracy, and it was also known at the time the invention was made that the art also fails to establish with great certainty the effectiveness of any specific detection method (McLeod H.L. *et al.* Eur J Cancer. 1999 Nov;35(12):1650-2).

With regards to factors three and seven, it is noted that the working examples of the instant application are limited to immunohistochemical analysis of Pin1 levels in

various tissues, the determination of its involvement in different pathways associated with cancer and to the comparison of tumor tissues in general to normal tissue. Such is not seen as sufficient to support the breadth of the claims, wherein the scope of the claims encompasses using other molecules, such as nucleic acids and protein, in the detection of abnormal cell growth. Furthermore, there is a lack of detailed explanation that distinctly points out the parameters needed to determine abnormal cell growth. It is noted that Law requires that the disclosure of an application shall inform those of skill in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Christopher Yaen
Art Unit 1642
March 22, 2002


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